

108TH CONGRESS
1ST SESSION

H. R. 3539

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, research, and medical management referral program for hepatitis C virus infection.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 19, 2003

Mrs. WILSON of New Mexico (for herself and Mr. TOWNS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, research, and medical management referral program for hepatitis C virus infection.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Hepatitis C Epidemic
5 Control and Prevention Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) Over 3,000,000 individuals in the United
2 States are chronically infected with the hepatitis C
3 virus (referred to in this section as “HCV”), making
4 it the Nation’s most common blood-borne viral infec-
5 tion.

6 (2) Nearly 2 percent of the population of the
7 United States has been infected with HCV.

8 (3) Conservative estimates indicate that ap-
9 proximately 35,000 Americans are newly infected
10 with HCV each year.

11 (4) HCV infection can cause life-threatening
12 liver disease.

13 (5) Individuals infected with HCV serve as a
14 source of transmission to others and, since few indi-
15 viduals are aware they are infected, are unlikely to
16 take precautions to prevent the spread or exacer-
17 bation of their infection.

18 (6) There is no vaccine available to prevent
19 HCV infection.

20 (7) Treatments are available to slow the pro-
21 gression of chronic HCV.

22 (8) An estimated 2,400,000 to 2,700,000 peo-
23 ple who are chronically infected with HCV are re-
24 ceiving no treatment.

1 (9) Conservative estimates place the costs of
2 lost productivity and medical care arising from
3 chronic HCV in the United States at more than
4 \$600,000,000 annually, and such costs will undoubt-
5 edly increase in the absence of expanded prevention
6 and treatment efforts.

7 (10) To combat the HCV epidemic in the
8 United States, the Centers for Disease Control and
9 Prevention developed Recommendations for Preven-
10 tion and Control of Hepatitis C Virus (HCV) Infec-
11 tion and HCV-Related Chronic Disease in 1998 and
12 the National Hepatitis C Prevention Strategy in
13 2001, and the National Institutes of Health con-
14 vened Consensus Development Conferences on the
15 Management of Hepatitis C in 1997 and 2002.
16 These recommendations and guidelines provide a
17 framework for HCV prevention, control, research,
18 and medical management referral programs.

19 (11) Federal support is necessary to increase
20 knowledge and awareness of HCV and to assist
21 State and local prevention and control efforts.

1 **SEC. 3. PREVENTION, CONTROL, AND MEDICAL MANAGE-**
 2 **MENT OF HEPATITIS C.**

3 Title III of the Public Health Service Act (42 U.S.C.
 4 241 et seq.) is amended by adding at the end the fol-
 5 lowing:

6 **“PART R—PREVENTION, CONTROL, AND MEDICAL**
 7 **MANAGEMENT OF HEPATITIS C**

8 **“SEC. 399AA. FEDERAL PLAN FOR THE PREVENTION, CON-**
 9 **TROL, AND MEDICAL MANAGEMENT OF HEPA-**
 10 **TITIS C.**

11 “(a) IN GENERAL.—The Secretary shall develop and
 12 implement a plan for the prevention, control, and medical
 13 management of hepatitis C (referred to in this part as
 14 ‘HCV’) which includes strategies for education and train-
 15 ing, surveillance and early detection, and research.

16 “(b) INPUT IN DEVELOPMENT OF PLAN.—In devel-
 17 oping the plan under subsection (a), the Secretary shall—

18 “(1) be guided by existing recommendations of
 19 the Centers for Disease Control and Prevention and
 20 the National Institutes of Health; and

21 “(2) consult with—

22 “(A) the Director of the Centers for Dis-
 23 ease Control and Prevention;

24 “(B) the Director of the National Insti-
 25 tutes of Health;

1 “(C) the Director of the Health Resources
2 and Services Administration;

3 “(D) the heads of other Federal agencies
4 or offices providing services to individuals with
5 HCV infections or the functions of which other-
6 wise involve HCV;

7 “(E) medical advisory bodies that address
8 issues related to HCV; and

9 “(F) the public, including—

10 “(i) individuals infected with HCV;
11 and

12 “(ii) advocates concerned with issues
13 related to HCV.

14 “(c) BIENNIAL UPDATE OF PLAN.—

15 “(1) IN GENERAL.—The Secretary shall con-
16 duct a biennial assessment of the plan developed
17 under subsection (a) for the purpose of incor-
18 porating into such plan new knowledge or observa-
19 tions relating to HCV and chronic HCV (such as
20 knowledge and observations that may be derived
21 from clinical, laboratory, and epidemiological re-
22 search and disease detection, prevention, and surveil-
23 lance outcomes) and addressing gaps in the coverage
24 or effectiveness of the plan.

1 “(2) PUBLICATION OF NOTICE OF ASSESS-
2 MENTS.—Not later than October 1 of the first even-
3 numbered year beginning after the date of enact-
4 ment of this part, and October 1 of each even-num-
5 bered year thereafter, the Secretary shall publish in
6 the Federal Register a notice of the results of the
7 assessments conducted under paragraph (1). Such
8 notice shall include—

9 “(A) a description of any revisions to the
10 plan developed under subsection (a) as a result
11 of the assessment;

12 “(B) an explanation of the basis for any
13 such revisions, including the ways in which such
14 revisions can reasonably be expected to further
15 promote the original goals and objectives of the
16 plan; and

17 “(C) in the case of a determination by the
18 Secretary that the plan does not need revision,
19 an explanation of the basis for such determina-
20 tion.

21 **“SEC. 399BB. ELEMENTS OF THE FEDERAL PLAN FOR THE**
22 **PREVENTION, CONTROL, AND MEDICAL MAN-**
23 **AGEMENT OF HEPATITIS C.**

24 “(a) EDUCATION AND TRAINING.—The Secretary,
25 acting through the Director of the Centers for Disease

1 Control and Prevention, shall implement programs to in-
2 crease awareness and enhance knowledge and under-
3 standing of HCV. Such programs shall include—

4 “(1) the conduct of health education, public
5 awareness campaigns, and community outreach ac-
6 tivities to promote public awareness and knowledge
7 about risk factors, the transmission and prevention
8 of infection with HCV, the value of screening for the
9 early detection of HCV infection, and options avail-
10 able for the treatment of chronic HCV;

11 “(2) the training of health care professionals
12 regarding the prevention, detection, and medical
13 management of hepatitis B (referred to in this part
14 as ‘HBV’) and HCV, and the importance of vacci-
15 nating HCV-infected individuals and those at risk
16 for HCV infection against the hepatitis A virus and
17 hepatitis B virus; and

18 “(3) the development and distribution of cur-
19 ricula (including information relating to the special
20 needs of individuals infected with HBV or HCV,
21 such as the importance of early intervention and
22 treatment and the recognition of psychosocial needs)
23 for individuals providing hepatitis counseling, as well
24 as support for the implementation of such curricula
25 by State and local public health agencies.

1 “(b) EARLY DETECTION AND SURVEILLANCE.—

2 “(1) IN GENERAL.—The Secretary, acting
3 through the Director of the Centers for Disease
4 Control and Prevention, shall support activities de-
5 scribed in paragraph (2) to promote the early detec-
6 tion of HCV infection, identify risk factors for infec-
7 tion, and conduct surveillance of HCV infection
8 trends.

9 “(2) ACTIVITIES.—

10 “(A) VOLUNTARY TESTING PROGRAMS.—

11 “(i) IN GENERAL.—The Secretary
12 shall support and promote the development
13 of State, local, and tribal voluntary HCV
14 testing programs to aid in the early identi-
15 fication of infected individuals.

16 “(ii) CONFIDENTIALITY OF TEST RE-
17 SULTS.—The results of an HCV test con-
18 ducted by a testing program developed or
19 supported under this subparagraph shall
20 be considered protected health information
21 (in a manner consistent with regulations
22 promulgated under section 264(c) of the
23 Health Insurance Portability and Account-
24 ability Act of 1996) and may not be used
25 for any of the following:

1 “(I) Issues relating to health in-
2 surance.

3 “(II) To screen or determine
4 suitability for employment.

5 “(III) To discharge a person
6 from employment.

7 “(B) COUNSELING REGARDING VIRAL HEP-
8 ATITIS.—The Secretary shall support State,
9 local, and tribal programs in a wide variety of
10 settings, including those providing primary and
11 specialty health care services in the private and
12 the public sectors, to—

13 “(i) provide individuals with informa-
14 tion about ongoing risk factors for HCV
15 infection with client-centered education
16 and counseling which concentrates on
17 changing behaviors that place them at risk
18 for infection; and

19 “(ii) provide individuals infected with
20 HCV with education and counseling to re-
21 duce the risk of harm to themselves and
22 transmission of the virus to others.

23 “(C) VACCINATION AGAINST VIRAL HEP-
24 ATITIS.—With respect to individuals infected, or

1 at risk for infection, with HCV, the Secretary
2 shall provide for—

3 “(i) the vaccination of such individ-
4 uals against hepatitis A virus, HBV, and
5 other infectious diseases, as appropriate,
6 for which such individuals may be at in-
7 creased risk; and

8 “(ii) the counseling of such individuals
9 regarding hepatitis A, hepatitis B, and
10 other viral hepatides.

11 “(D) MEDICAL REFERRAL.—The Secretary
12 shall support—

13 “(i) referral of persons infected with
14 or at risk for HCV, for drug or alcohol
15 abuse treatment where appropriate; and

16 “(ii) referral of persons infected with
17 HCV—

18 “(I) for medical evaluation to de-
19 termine their stage of chronic HCV
20 and suitability for antiviral treatment;
21 and

22 “(II) for ongoing medical man-
23 agement of HCV.

24 “(3) HEPATITIS C COORDINATORS.—The Sec-
25 retary, acting through the Director of the Centers

1 for Disease Control and Prevention, shall, upon re-
2 quest, provide a Hepatitis C Coordinator to a State
3 health department in order to enhance the additional
4 management, networking, and technical expertise
5 needed to ensure successful integration of HCV pre-
6 vention and control activities into existing public
7 health programs.

8 “(c) SURVEILLANCE AND EPIDEMIOLOGY.—

9 “(1) IN GENERAL.—The Secretary shall pro-
10 mote and support the establishment and mainte-
11 nance of State HCV surveillance databases, in order
12 to—

13 “(A) identify risk factors for HCV infec-
14 tion;

15 “(B) identify trends in the incidence of
16 acute and chronic HCV;

17 “(C) identify trends in the prevalence of
18 HCV infection among groups that may be dis-
19 proportionately affected by HCV, including in-
20 dividuals living with HIV, military veterans,
21 emergency first responders, racial or ethnic mi-
22 norities, and individuals who engage in high
23 risk behaviors, such as intravenous drug use;
24 and

1 “(D) assess and improve HCV infection
2 prevention programs.

3 “(2) SEROPREVALENCE STUDIES.—The Sec-
4 retary shall conduct a population-based
5 seroprevalence study to estimate the current and fu-
6 ture impact of HCV. Such studies shall consider the
7 economic and clinical impacts of HCV, as well as the
8 impact of HCV on quality of life.

9 “(3) CONFIDENTIALITY.—Information con-
10 tained in the databases under paragraph (1) or de-
11 rived through studies under paragraph (2) shall be
12 de-identified in a manner consistent with regulations
13 under section 264(c) of the Health Insurance Port-
14 ability and Accountability Act of 1996.

15 “(d) RESEARCH NETWORK.—The Secretary, acting
16 through the Director of the Centers for Disease Control
17 and Prevention and the Director of the National Institutes
18 of Health, shall—

19 “(1) conduct epidemiologic research to identify
20 best practices for HCV prevention;

21 “(2) establish and support a Hepatitis C Clin-
22 ical Research Network for the purpose of conducting
23 research related to the treatment and medical man-
24 agement of HCV; and

1 “(3) conduct basic research to identify new ap-
2 proaches to prevention (such as vaccines) and treat-
3 ment for HCV.

4 “(e) REFERRAL FOR MEDICAL MANAGEMENT OF
5 CHRONIC HEPATITIS C.—The Secretary shall support and
6 promote State, local, and tribal programs to provide HCV-
7 positive individuals with referral for medical evaluation
8 and management, including currently recommended
9 antiviral therapy when appropriate.

10 “(f) UNDERSERVED AND DISPROPORTIONATELY AF-
11 FECTED POPULATIONS.—In carrying out this section, the
12 Secretary shall provide expanded support for individuals
13 with limited access to health education, testing, and health
14 care services and groups that may be disproportionately
15 affected by HCV.

16 “(g) EVALUATION OF PROGRAM.—The Secretary
17 shall develop benchmarks for evaluating the effectiveness
18 of the programs and activities conducted under this sec-
19 tion and make determinations as to whether such bench-
20 marks have been achieved.

21 **“SEC. 399CC. GRANTS.**

22 “(a) IN GENERAL.—The Secretary may award grants
23 to, or enter into contracts or cooperative agreements with,
24 States, political subdivisions of States, Indian tribes, or

1 nonprofit entities that have special expertise relating to
 2 HCV, to carry out activities under this part.

3 “(b) APPLICATION.—To be eligible for a grant, con-
 4 tract, or cooperative agreement under subsection (a), an
 5 entity shall prepare and submit to the Secretary an appli-
 6 cation at such time, in such manner, and containing such
 7 information as the Secretary may require.

8 **“SEC. 399DD. AUTHORIZATION OF APPROPRIATIONS.**

9 “There are authorized to be appropriated to carry out
 10 this part \$90,000,000 for fiscal year 2004, and such sums
 11 as may be necessary for each of fiscal years 2005 through
 12 2008.”.

13 **SEC. 4. LIVER DISEASE RESEARCH ADVISORY BOARD.**

14 Part B of title IV of the Public Health Service Act
 15 (42 U.S.C. 284 et seq.) is amended by adding at the end
 16 the following:

17 **“SEC. 409J. LIVER DISEASE RESEARCH ADVISORY BOARD.**

18 “(a) ESTABLISHMENT.—Not later than 90 days after
 19 the date of enactment of this section, the Director of the
 20 National Institutes of Health shall establish a board to
 21 be known as the Liver Disease Research Advisory Board
 22 (referred to in this section as the ‘Advisory Board’).

23 “(b) DUTIES.—The Advisory Board shall advise and
 24 assist the Director of the National Institutes of Health
 25 concerning matters relating to liver disease research, in-

cluding by developing and revising the Liver Disease Research Action Plan.

“(c) VOTING MEMBERS.—The Advisory Board shall be composed of 18 voting members to be appointed by the Director of the National Institutes of Health, in consultation with the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, of whom 12 such individuals shall be eminent scientists and 6 such individuals shall be lay persons. The Director of the National Institutes of Health, in consultation with the Director of the Institute, shall select 1 of the members to serve as the Chair of the Advisory Board.

“(d) EX OFFICIO MEMBERS.—The Director of the National Institutes of Health shall appoint each director of a national research institute that funds liver disease research to serve as a nonvoting, ex officio member of the Advisory Board. The Director of the National Institutes of Health shall invite 1 representative of the Centers for Disease Control and Prevention, 1 representative of the Food and Drug Administration, and 1 representative of the Department of Veterans Affairs to serve as such a member. Each ex officio member of the Advisory Board may appoint an individual to serve as that member’s representative on the Advisory Board.

“(e) LIVER DISEASE RESEARCH ACTION PLAN.—

1 “(1) DEVELOPMENT.—Not later than 15
2 months after the date of the enactment of this sec-
3 tion, the Advisory Board shall develop (with appro-
4 priate support from the Director) a comprehensive
5 plan for the conduct and support of liver disease re-
6 search to be known as the Liver Disease Research
7 Action Plan. The Advisory Board shall submit the
8 Plan to the Director of NIH and the head of each
9 institute or center within the National Institutes of
10 Health that funds liver disease research.

11 “(2) CONTENT.—The Liver Disease Research
12 Action Plan shall identify scientific opportunities
13 and priorities of liver disease research necessary to
14 increase understanding of and to prevent, cure, and
15 develop better treatment protocols for liver diseases.

16 “(3) REVISION.—The Advisory Board shall re-
17 vise every 2 years the Liver Disease Research Action
18 Plan, but shall meet annually to review progress and
19 to amend the Plan as may be appropriate because
20 of new scientific discoveries.”.

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